

REMARKS

New claim 65 has been added. Claims 1, 5-30, and 35-65 are pending. In the Office Action, claims 1, 5-30, and 35-64 were rejected in a obviousness-type double patenting rejection based on claims 1-68 of U.S. Patent No. 6,723,306; claims 1, 5-30, and 35-64 were rejected in a provisional obviousness-type double patenting rejection based on claims 1-55 of Application No. 10/107,410; claims 9, 11, and 14 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite; claims 1, 6-11, 14, 16, 18, 25-30, 39-41, 43, 45-48, and 51-59 were rejected under 35 U.S.C. § 102(e) based on U.S. Patent No. 5,965,276 to Shlenker et al. ("Schlenker"); claims 5, 15, 17, 19-24, 35-38, 42, 49, 50, and 60 were rejected under 35 U.S.C. § 103(a) based on Shlenker in view of WO 98/18441 to Fowler et al. ("Fowler"); claim 44 was rejected under 35 U.S.C. § 103(a) based on Shlenker in view of U.S. Patent No. 6,338,839 to Auguste et al. ("Auguste"); and claims 12, 13, and 61-64 were rejected under 35 U.S.C. § 103(a) based on Shlenker in view of JP04-108710. Applicant respectfully traverses these rejections and requests that they be withdrawn for the reasons discussed below.

Double Patenting Rejections

Applicant submits that the provisional obviousness-type double patenting rejection based on Application No. 10/107,410 and the obviousness-type double patenting rejection based on U.S. Patent No. 6,723,306 are obviated by the Terminal Disclaimer filed concurrently with this Reply.

Rejections under 35 U.S.C. § 112

Applicant respectfully traverses the rejection of claims 9, 11, and 14 under 35 U.S.C. § 112, second paragraph. The Office Action alleges that the terms “freeze-dried substances,” “wetting agents,” “healing agents,” “vascular protectors,” and “skin conditioners” recited in claims 9 and 11 do not set forth the metes and bounds of the claimed invention.

Applicant submits that the claims fully comply with all of the requirements of § 112, second paragraph. In order to establish a rejection under 35 U.S.C. § 112, second paragraph for indefiniteness, one of ordinary skill in the art must be unable to determine the metes and bounds of the claimed invention. See M.P.E.P. § 2173.02. In such cases, the Examiner is required to provide “an analysis as to why the phrase(s) used in the claim is ‘vague and indefinite’ should be included in the Office action.” M.P.E.P. § 2173.02.

Applicant respectfully submits that the terms “freeze-dried substances,” “wetting agents,” “healing agents,” “vascular protectors,” and “skin conditioners” in claims 9 and 11 are common terms known to persons of ordinary skill in the art, and cannot, therefore, be indefinite. Moreover, contrary to M.P.E.P. § 2173.02, the Office Action fails to provide any analysis or evidence supporting the allegation of indefiniteness.

The Office Action also alleges that the recitation of the term “vinyl” as an adhesive in claim 14 fails to set forth the metes and bounds of the claim. Applicant respectfully directs the Examiner’s attention to claim 14’s entire recitation of “a

permanent adhesive comprising one of vinyl, PVA, PVP, pseudo-latex, an acrylic polymer, a polyurethane, and a latex elastomer.” As the Examiner is undoubtedly aware, the term “comprising” is an open-ended term, allowing the claimed invention to include additional components not recited in the claims. As such, Applicant submits that the recitation of “vinyl” relates to a permanent adhesive with vinyl as at least one component, and not necessarily an adhesive having only “vinyl” alone.

For at least these reasons, the rejections under 35 U.S.C. § 112, second paragraph should be withdrawn.

Rejection under 35 U.S.C. § 102

Applicant respectfully traverses the rejection of claims 1, 6-11, 14, 16, 18, 25-30, 39-41, 43, 45-48, and 51-59 under 35 U.S.C. § 102(e) based on Shlenker because Schlenker fails to disclose each and every claimed limitation. For example, Schlenker fails to disclose “at least one adhesive matrix between the two non-adhesive layers, ... the two non-adhesive layers being ... bonded to the adhesive matrix, the adhesive matrix containing at least one active agent that is soluble in said solvent, wherein ... when the composite structure is wetted by the solvent, the active agent is released from the adhesive matrix and diffuses towards the surface region,” as recited in independent claims 1, 54, 55 and 56. Schlenker also fails to disclose an “adhesive matrix containing at least one active agent, the active agent being released when the composite structure is wetted by a solvent; ... the first non-adhesive layer and the second non-adhesive layer being ... bonded together by the adhesive matrix,” as recited in claim 27.

The Office Action attempts to equate Schlenker's needle treatment layer with an adhesive matrix. Page 5. The sole disclosed purpose of the needle treatment layer is to coat or clean a needle that has punctured a membrane. Col. 5, lines 13-23.

Schlenker includes two embodiments having a needle treatment layer. In one embodiment including a small adhesive backed patch or disc that can be attached to the area which the needle is set to penetrate, the adhesive is disposed only on the outer periphery, and not "between the two non-adhesive layers." See col. 5, lines 42-46.

In the second embodiment, Schlenker discloses a needle treatment layer including an adhesive or film-forming material which would form a physical sheath or additional membrane over the needle or other sharp object. See col. 5, lines 13-16. In such an embodiment, Schlenker does not disclose "when the composite structure is wetted by the solvent, the active agent is released from the adhesive matrix and diffuses towards the surface region." Rather, there is only a layer that functions when a needle or other object compromises the integrity of the device by piercing through any layers. See col. 4, lines 59-61.

Additionally, Schlenker simply fails to disclose "at least one adhesive matrix between the two non-adhesive layers, ... the two non-adhesive layers being ... bonded to the adhesive matrix." Schlenker actually teaches away from bonding first and second non-adhesive layers with an adhesive layer, and discloses several means for selectively bonding layers of a glove or condom at a cuff region and other areas to preserve chambers for a reservoir of material between the layers. See col. 8, lines 29-31; col. 12, lines 45-47. Schlenker specifically teaches discrete chambers between the

layers. Col. 13, lines 19-21; col. 12, lines 52-53. And Schlenker actually teaches the uses of a surfactant to prevent fusing of layers. Col. 12, lines 19-21. Thus, Schlenker fails to disclose an “at least one adhesive matrix between the two non-adhesive layers, ... the two non-adhesive layers being ... bonded to the adhesive matrix.”

For at least these reasons, claims 1, 27, 54, 55, and 56 are allowable over Schlenker. Claims 6-11, 14, 16, 18, 25, 26, 28-30, 39-41, 43, 45-48, 51-53, and 57-59 are allowable at least due to their dependence on an allowable claim. Applicant therefore requests that the rejection of claims 1, 6-11, 14, 16, 18, 25-30, 39-41, 43, 45-48, and 51-59 over Schlenker be withdrawn and that the claims be allowed.

Rejections under 35 U.S.C. § 103

The rejection of claims 5, 15, 17, 19-24, 35-38, 42, 49, 50, and 60 under 35 U.S.C. § 103(a) based on Shlenker in view of Fowler fails to establish a *prima facie* case of obviousness at least because neither reference, either alone or in combination, discloses or suggests each and every element of the claims. As discussed above, Schlenker fails to disclose all of the claim elements as recited in independent claims 1 and 56, from which each of the rejected claims depends. Fowler does not correct the deficiencies, and is not cited in the Office Action as doing so. For at least this reason, claims 5, 15, 17, 19-24, 35-38, 42, 49, 50, and 60 are allowable.

Similarly, the rejection of claim 44 under 35 U.S.C. § 103(a) based on Shlenker in view Auguste fails to establish a *prima facie* case of obviousness at least because neither reference, either alone or in combination, discloses or suggests each and every

element of the claims. As discussed above, Schlenker fails to disclose all of the claim elements as recited in independent claim 1, from which claim 44 depends. Auguste does not correct the deficiencies, and is not cited in the Office Action as doing so. For at least this reason, claim 44 is allowable.

The rejection of claims 12, 13, and 61-64 under 35 U.S.C. § 103(a) based on Shlenker in view of JP04-108710 fails to establish a *prima facie* case of obviousness at least because neither reference, either alone or in combination, discloses or suggests each and every element of the claims. As discussed above, Schlenker fails to disclose all of the claim elements as recited in independent claim 1, from which claims 12 and 13 depend. JP04-108710 does not correct the deficiencies, and is not cited in the Office Action as doing so. For at least this reason, claims 12 and 13 are allowable.

With respect to claims 61-64, neither Schlenker nor JP04-108710 discloses or suggests “at least one adhesive matrix between the two support layers, the two support layers being permanently bonded to the adhesive matrix,” as recited in independent claim 61. As discussed above, Schlenker fails to disclose two layers permanently bonded to an adhesive matrix. JP04-108710 does not correct the deficiencies, and is not cited in the Office Action as doing so. For at least this reason, claim 61 is allowable. Claims 62-64 are allowable at least due to their dependence on claim 61.

Conclusion

By this amendment, new claim 65 is added. Claim 65 is allowable over the cited art for at least reasons similar to those discussed above for claim 1, and is allowable at least due to its dependence on an allowable claim.

Applicants respectfully request reconsideration of this application, withdrawal of the claim rejections, and the timely allowance of the pending claims.

The Office Action contains numerous characterizations of the pending claims, the claims of U.S. Patent No. 6,723,306 and U.S. Application No. 10/107,410 and the related art, with which Applicant does not necessarily agree. Unless expressly noted otherwise, Applicant declines to subscribe to any statement of characterization in the Office Action.


Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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